# ANDERSON EXHIBIT 35

FOOD MARKETING INSTITUTE

January 2, 2008

**Via Courier**

Mr. Kerry Weems
Acting Administrator
Centers for Medicare and Medicaid Services
Room 445–G
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, DC 20201

**RE: Final Rule to Implement Provisions of DRA Pertaining to Prescription Drugs under the Medicaid Program; Medicaid Program; Prescription Drugs (CMS–2238–FC, July 17, 2007).**

Dear Mr. Weems:

The Food Marketing Institute (FMI) appreciates the opportunity to comment on the Centers for Medicare and Medicaid Services (CMS) final rule to implement provisions of the Deficit Reduction Act (DRA) related to prescription drugs reimbursed under the Medicaid Program ("Final Rule").[1] As we stated in our response to the proposed rule, FMI is very concerned about the impact of the rule on its supermarket pharmacy members. We are heartened that CMS made some positive changes to the rule in response to comments, but we believe that much improvement is still needed to avoid serious problems for the Medicaid program. Our comments and further recommendations are discussed more fully below.

FMI conducts programs in research, education, industry relations and public affairs on behalf of its 1,500 member companies – food retailers and wholesalers – in the United States and around the world. FMI's U.S. members operate approximately 26,000 retail food stores with a combined annual sales volume of $340 billion – three-quarters of all retail food store sales in the United States. FMI's retail membership is composed of large multi-store chains, regional firms and independent supermarkets. Its international membership includes 200 companies from 50 countries.

FMI's retail members also operate more than 19,000 in-store pharmacy departments. We estimate that supermarket pharmacies account for nearly 14 percent of all outpatient prescription drugs dispensed in the United States. Based on current industry trends toward larger store formats

[1] 72 Fed. Reg. 39142 (July 17, 2007).

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and the convenience of one-stop shopping, we anticipate that the number of pharmacies located in supermarkets will continue to increase in the coming years, as will the number of prescriptions that are dispensed on an outpatient basis from these community settings.

In the balance of this letter, we urge CMS to consider changes to the pharmacy reimbursement policies it has adopted in its final rule, centering mainly on the definition of Average Manufacturer Price (AMP) as it relates to the calculation of the Federal Upper Limit (FUL) for generic drugs. Specifically, we believe that:

- The inclusion of mail-order prices and other prices that are outside of the retail pharmacy class of trade in AMP is inappropriate;
- CMS acted appropriately in excluding Pharmacy Benefit Manager (PBM) discounts, discounts to State Pharmacy Assistance Programs (S-PAPs) and discounts to Part D plans from AMP;
- CMS should use its discretion to use the weighted average of AMPs to set FULs, rather than the lowest cost therapeutic alternative;
- CMS should not publish AMP data until the revisions to the AMP calculation are fully understood;
- The agency should improve its outlier policy to reduce volatility in FULs and ensure that FULs are based on prices truly available to retail pharmacies;
- FULs should be based on prices that are available nationally; and
- CMS must take additional steps to ensure the adequacy of Medicaid dispensing fees at the state level.

**A. Policy Context**

As we discussed in our comments to the proposed rule, supermarket pharmacy profit margins are in the range of approximately two to three percent of total revenues—a far lower percentage than most other businesses. Efforts to reduce pharmacy reimbursement levels should be viewed with extreme caution; the DRA cuts, particularly as implemented by CMS, are too severe. FMI and its members were quite disturbed by recent estimates that as many as 12,000 pharmacies could fail if the CMS final rule is implemented without changes.[2] Consequently, we are pleased by the recent decision of the District of Columbia Court of Appeals to enjoin the use of AMP in setting the FUL and to prevent publication of AMP data in its current form. Significant improvements are needed before these policies can be safely implemented.

[2] *National Association of Chain Drug Stores et al. v. Michael O. Leavitt, Secretary of Health and Human Services et al.*, No. 1:07-cv-02017-RCL, expert report of Stephen W. Schondelmeyer, Pharm.D., Ph.D., http://www.nacds.org/user-assets/pdfs/newsrelease/FINAL_DRA_PI_Report_SWS11-14-07.pdf (Accessed January 2, 2008).

FMI appreciates the difficult balance that CMS has attempted to strike between the use of AMP for the reimbursement purposes dictated by the DRA and the use of AMP in the calculation of manufacturer rebates to the Medicaid program. Along with others in the pharmacy community, FMI continues to support efforts to address this problem legislatively. Various proposals have been introduced to address the cuts to pharmacy reimbursement that the CMS rule would cause. Some would use new benchmarks for pharmacy reimbursement, while others would clarify Congressional intent about the discounts included within AMP, while making other improvements. However, as we discuss in the balance of this letter, CMS has significant discretion under the current statute to mitigate the severity of the problem—discretion that it has not fully exercised. We urge CMS to emphasize the role of AMP as a reimbursement benchmark in the final rule to ensure that our member pharmacies can continue to serve Medicaid patients.

**B. Continued inclusion of mail-order pharmacies in the retail class of trade is inappropriate**

In our letter in response to the proposed rule,[3] we urged CMS to revise the proposed AMP definition to exclude sales to mail order and Pharmacy Benefit Managers (PBMs). We are pleased that CMS decided to remove PBMs from the definition of retail class of trade, and we agree with the logic that "rebates, discounts or other price concessions to PBMs should not be included in AMP because . . . they do not adjust the price actually realized" by the manufacturer.[4] We still believe, however, that the inclusion of mail order pharmacies is problematic.

As we stated before, Section 1927(k)(1) of the Social Security Act is very clear. AMP is the *average* price paid to the manufacturer for the drug in the United State *by wholesalers* for drugs *distributed to the retail pharmacy class of trade*. Mail order pharmacies fall outside the retail class of trade. We disagree with the agency's implication in the final rule that excluding mail order pharmacies would result in an unnecessarily narrow definition of the retail class of trade. We note again that previous policies to include mail-order pharmacies in AMP were developed when AMP was not used for pharmacy reimbursement purposes, but only for the purpose of calculating rebates owed by manufacturers to CMS and the states. Accordingly, CMS is not bound by its past policy, nor should the agency feel constrained to operate within it. Rather, CMS should define retail pharmacy class of trade in a parallel manner to the definition used for Medicare Part D. The inclusion of mail order prices that are clearly not accessible to retail pharmacies artificially deflates AMP, potentially impeding the convenient access of Medicaid beneficiaries to supermarket pharmacies if these retail outlets cannot receive adequate reimbursement for their pharmaceutical acquisition costs for generic drugs.

[3] FMI Letter to Leslie Norwalk February 20, 2007.
[4] Final Rule at 39167.

**C. CMS correctly excludes sales to S-PAPs and Part D Plans from the calculation of AMP**

Just as FMI approves of the decision to exclude PBMs, we applaud the decision to exclude sales from State Pharmacy Assistance Program (S-PAPs) and Part D plans from the definition of AMP. CMS is correct in excluding these sales since retail pharmacists are unlikely to receive discounts available to these entities.

**D. CMS should use the weighted average of AMPs to set FULs, rather than the lowest cost therapeutic alternative**

As we stated in our comments on the proposed rule, CMS has the discretion to use a weighted average of all therapeutic alternatives of a particular prescription drug when setting a FUL. Particularly in light of the GAO's findings that AMP-based FULs are below pharmacy acquisition costs, the use of a weighted average could mitigate the number of instances where pharmacies are to be reimbursed below their acquisition costs. CMS should reconsider its decision to use the lowest cost therapeutic alternative.

**E. CMS should delay publication of AMP data**

As FMI stated in its comments on the proposed rule, the publication of AMP data is highly likely to distort the marketplace for generic drugs, with potentially serious anti-competitive effects; the decision of the Court of Appeals for the District of Columbia Circuit to enjoin CMS from disseminating AMP data confirms our position.[5] Publishing AMP data could create a floor on the price discounts that generic manufacturers are willing to offer, thus reducing the level of competition between generic manufacturers with potentially significant negative effects on the Medicaid program.

If AMP data were to be published, manufacturers may find it difficult to offer discounts to some customers and not to others, as most customers will be unwilling to pay more than the average price. In this scenario, manufacturers will be more likely to sell to all buyers at the same rates, eliminating the benefits of competition that could otherwise accrue to the marketplace. In the case of Medicaid, the government will bear most of the consequences of this reduced competition – the prices paid to manufacturers on average will increase, driving AMP-based reimbursement up also.

FMI continues to work towards a legislative vehicle to ensure that AMP data remain confidential. However, even if the court's injunction is lifted before a statutory change is codified, CMS should exercise its discretion to delay the publication of AMP data until the implications of the revised definition of AMP are fully understood.

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[5] *National Association of Chain Drug Stores et al. v. Michael O. Leavitt, Secretary of Health and Human Services et al.*, No. 1:07-cv-02017-RCL, Document 36 (District of Columbia Circuit Court, December 19, 2007).

**F. CMS' changes to the outlier policy show some progress, but more improvements are needed**

In our comments to the proposed rule, FMI expressed concern that CMS' proposal to set each FUL based on the lowest AMP "that is not less than 30 percent of the next highest AMP for that drug" would still capture and incorporate a wide range of outliers in AMP-based FULs. We see the decision to expand the outlier policy to 40 percent as a step in the right direction. However, to reduce volatility and ensure a nationally available AMP, CMS should set the FUL based on an AMP that is not more than 10 percent below the next highest AMP. A wider gap between therapeutic alternatives would likely be indicative of problems in AMP data or temporary spikes that would not actually reflect prices nationally available in the marketplace. Using a small percentage range will also improve the ability of pharmacists to purchase prescription drugs at prices below the FUL and better serve the agency's stated purpose of ensuring that drugs are "nationally available at the FUL price."

**G. CMS should ensure that FULs are based on AMPs that are available nationally**

Especially if CMS does not adopt our proposal to base FULs on the weighted average of various generic alternatives, the agency must ensure that no FUL is based on an AMP for a generic pharmaceutical produced by a manufacturer that does not make the product nationally available. It is common for generic manufacturers to work directly with select pharmacy chains and wholesalers to meet market share goals in a manner that may not provide national access to their products. Consistent with others in the industry, FMI believes that AMP should only be calculated based on generic products that are AB-rated in the FDA *Orange Book* and are consistently available from the three major national wholesalers in supplies adequate to afford national distribution. Products that are erratically available or that are available only in limited supplies should be excluded from the weighted average AMP calculation. We are particularly concerned that a FUL could be set by a manufacturer undercutting the market, but without enough supply to meet market demands for an extended period of time. Particularly if CMS does not move to a FUL based on weighted average AMP, we would urge the agency to take steps to ensure that each AMP used to represent a FUL reflects a product that continues to be nationally available to all retail pharmacies.

**H. CMS has not taken necessary steps to ensure adequate state dispensing fees**

In the final rule, CMS responded to comments urging the agency to require states to include reasonable margins for pharmacies in their definition of dispensing fees by indicating that the factors it has identified for inclusion in state dispensing fees already include reasonable margins.[6] CMS went on to state that it will review State Plan Amendments for reasonableness in any changes to dispensing fees and will encourage states to review their dispensing fee methodology when

[6] Final Rule at 39161.

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making changes to ingredient cost reimbursement. However, no specific methodology will be required. FMI believes that these steps are not enough to ensure adequate state dispensing fees.

As we noted before, in order to protect convenient access to prescription drugs for Medicaid beneficiaries, the definition of dispensing fee should be amended to include medication therapy management services and a reasonable return for pharmacies. As Medicaid may no longer adequately reimburse pharmacies for the ingredient costs of generic drugs, setting dispensing fees adequate to cover pharmacy costs in delivering pharmaceuticals to Medicaid beneficiaries is absolutely essential.

According to various sources, the current average dispensing fee at the state level is approximately $4.50. Recent studies of the actual costs to pharmacists to dispense prescription drugs have placed those dispensing costs at between $9 and $14 per prescription, depending on the state, with a national average of more than $10.[7] Thus, dispensing fees at the state level are clearly inadequate to cover pharmacy costs.

Accordingly, CMS should require each state to make a specific finding that the existing dispensing fee structure is not only adequate to cover pharmacy costs (including a reasonable return), but also that these fees provide adequate incentives for generic usage in light of the revised FUL policy. CMS should direct states to increase those dispensing fees that are too low to encourage adequate generic usage.

**I. Conclusion**

FMI appreciates the opportunity to offer these comments on the impact that CMS' proposed regulation will have on supermarket pharmacies. We respectfully request that you consider our comments fully on the record.

We look forward to working with CMS on these issues in the future. Please feel free to call me or Cathy Polley, FMI's Vice President for Pharmacy Services at (202) 220-0631, with any questions you might have.

Sincerely,

Tim Hammonds
President and CEO

[7] "National Study to Determine the Cost of Dispensing Prescriptions in Community Retail Pharmacies", Grant Thorton LLP (January 2007). Also, C. Mullins and A. Davidoff, et al, "Analysis of Cost of Prescription Drug Dispensing in Maryland" (December 2006).

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